GMO Authorisations and The Aarhus Regulation: Paving The Way for Precautionary GMO Governance?

Abstract

This article endeavours to assess whether existing case law under the Aarhus Regulation has opened up any opportunities for civil society to challenge the decision that, in the face of scientific uncertainty, GMO risks meet the intended EU level of health and environmental protection. Against this backdrop, it seeks to establish whether the actions of NGOs under the Aarhus Regulation have resulted in any meaningful review of the Commission's exercise of its discretion, in accordance with the overarching tenets of the precautionary principle and the aim of a high level of health and environmental protection. Upon an in depth analysis of the recent *TestBioTech* cases the article puts forward an argument for different evidentiary rules and a different standard of review in Aarhus Regulation case law, advocating a clearer distinction between 'standard' action for annulment and annulment of a decision to reject a request for internal review. This is argued to be the only way forward to breathe some life into the Aarhus Regulation's provisions, ensuring some scrutiny of the level of protection achieved and nudging the Commission to take the precautionary principle seriously in the GMO field.

Keywords: Judicial review, Aarhus Regulation, GMOs, precautionary principle.

1. The Aarhus Regulation, The Notion of Socially Acceptable Risk and GMOs.

An evidence-based and a socially acceptable risk approach coexist under EU risk regulation.[1] Under the former approach the results of technical risk assessment directly feed into risk management; little or no room for manoeuvre is thus left for risk managers to take scientific uncertainty, the precautionary principle[2] or any of the other legitimate factors ('OLFs') at stake[3] into consideration. The specific values at issue, the pervasiveness of the potential effects,

[1] Giulia Claudia Leonelli, 'The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: *Bilbaína*' (2018) *Common Market Law Review* 55(4), 1217-1250; Giulia Claudia Leonelli, 'The Glyphosate Saga and The Fading Democratic Legitimacy of European Union Risk Regulation' (2018) *Maastricht Journal of European and Comparative Law*, 1-25. For a different perspective on the coexistence of an 'evidence-based' and 'precautionary' soul under EU risk regulation see Alberto Alemanno, 'Risk Versus Hazard and The Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt' (2011) *European Journal of Risk Regulation* 2(1), 169-172.

[2] See first and foremost article 191(2) TFEU and European Commission, Communication from the Commission on the Precautionary Principle, COM (2000) 1 final, at 12, 13 and 16.

[3] On the role of OLFs in EU risk regulation, see for instance recital (19) and articles 5, 6(2), 6(3) and 7(2) of the General Food Law ('GFL'), Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002] OJ L31. Article 6(3) maintains that 'risk management shall take into account the results of risk assessment […], other factors legitimate

the intended level of protection in the field, public opinion or the availability and efficacy of risk management measures have no role to play; factors such as the advantages and disadvantages associated with the decision to run uncertain risks and their distribution across different constituencies are equally irrelevant.[4] Evidence-based risk regulation in the EU draws on the dominant transnational legal narrative, whereby uncertain risks *ought to* be run as long as they have *not* been scientifically proved and established.[5]

Under a socially acceptable risk approach, on the other hand, the decision to run uncertain risks and the enactment of risk management measures result from an iterative evaluation of all factors at stake.[6] At the heart of this approach is the question whether uncertain risks are worth running in the light of scientific uncertainty, the intended level of protection pursued, the public health and environmental values at issue as well as all relevant advantages, disadvantages and distributional stakes.[7] Under this approach, the presumption that uncertain risks ought to be run unless they have been positively proved does not apply. Rather, risk managers are called upon to make a convincing case that a product or process *meets* the intended level of protection and is *safe enough* for the ensuing risks to be *socially acceptable* and *worth running*, taking all factors into due consideration.

Despite the gradual evidence-based shift in EU risk regulation, socially acceptable risk approaches are alive and well. The EU-wide battles of societal stakeholders and NGO actors are a testament to political and socio-economic contestation over the notions of 'acceptable risk' and 'intended EU level of protection'. The GMO dilemma is probably the best exemplification of this tension between evidence-based and socially acceptable risk models, technocratic expertise and political and democratic legitimacy,[8] hegemonic and counter-hegemonic legal narratives on whether and how uncertain health and environmental risk should

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to the matter under consideration, and the precautionary principle where the conditions laid down in article 7(1) are relevant […]'.

[4] More specifically, under evidence-based approaches to risk regulation, cost-benefit analysis (CBA) heuristics apply to the phase of risk management. Any detailed analysis of this aspect would go beyond the limited scope of this article; for more information see Giulia Claudia Leonelli, 'GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives' (2018) *Transnational Legal Theory* 9(3), 302-315.

[5] In this perspective see Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) *Current Legal Problems* 62(2), 242-285; Giulia Claudia Leonelli, 'GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives', supra no. 4; and Giulia Claudia Leonelli, *The Transnational Law and Governance of GMOs* (under peer review, on file with author).

[6] On 'linear' and 'iterative' approaches to risk regulation see Elizabeth Fisher, 'Framing Risk Regulation: A Critical Reflection' (2013) *European Journal of Risk Regulation* 4(2), 125-132.

[7] See also Giulia Claudia Leonelli, 'The Glyphosate Saga and The Fading Democratic Legitimacy of European Union Risk Regulation', supra no. 1.

[8] For the famous conceptualisation of their balance under EU risk regulation, see Case T-13/99 *Pfizer Animal Health SA v Council* EU:T:2002:209.

be regulated in the EU.[9] Despite legal reforms[10] and repeated struggles to build multi-level and inter-institutional deliberative practices[11] the GMO authorisation process is still, after almost twenty years since the enactment of the applicable regulatory framework, plagued by dissent and controversy. Whilst EU institutions have continuously pointed to the lack of positive scientific proof of health and environmental risks, civil society within and across EU Member States has repeatedly and consistently argued that the risks posed by agricultural biotechnologies are neither socially acceptable nor worth running. In this light, the GMO conundrum boils down to a substantive clash between evidence-based and socially acceptable risk approaches to the governance of agricultural biotechnologies.

Internal review and access to justice under the Aarhus Regulation[12] play a particularly important role in highly controversial cases, such as the one of GMOs. Unsurprisingly, over the past few years, these provisions have been repeatedly and increasingly deployed by NGO actors to challenge EU authorisations of GM varieties. Article 10 of the Aarhus Regulation entitles NGOs to make a written request for internal review to the EU institution or body which has adopted an administrative act under environmental law or omitted to do so. The aim is to enable NGOs to challenge the decision of the EU institution, providing evidence that it should be reviewed. Yet, a decision to grant internal review does not necessarily result in the repeal or withdrawal of the administrative act; the EU institution or body may suspend it, amend it or request further scientific evidence.

Article 12 states that NGOs whose request for internal review has been rejected may institute proceedings before the Court of Justice, in accordance with the relevant Treaty provisions; in other words, they may seek the annulment of the decision rejecting their request for internal review. In this case, NGOs will only challenge the decision taken through the administrative act indirectly. The object of the action for annulment is the decision rejecting the NGOs'

[9] See Giulia Claudia Leonelli, 'GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives', supra no. 4; in the same perspective see Maria Lee, *EU Regulation of GMOs* (Edward Elgar 2008).

[10] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 Amending Directive 2001/18/EC as regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in their Territory OJ [2015] L68/1.

[11] For a different reading of the GMO dilemma through the procedural perspective of 'deliberative' and 'control' models see inter alia Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance - GMO Regulation and Its Reform' (2015) *European Law Journal* 21(5), 622-640.

[12] Regulation (EC) No. 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters to Community Institutions and Bodies, O.J. 2006 L 264/13.

request for internal review, and the annulment of the latter does by no means lead to the annulment of the administrative act adopted under EU environmental law.

On the one hand, the Aarhus Regulation provisions can reinforce and breathe new life into the political and democratic component of EU risk regulation, at a time when EU institutions have moved further down the road of technocratic evidence-based regulation.[13] Giving NGO actors the power to request the internal review of GMO authorisations and enabling them to seek the annulment of the ensuing decision opens up new spaces for public participation, re-democratising GMO governance in *procedural* terms.

On the other hand, and focusing on the *substantive* outcome of the review process, the access to justice pillar of the Aarhus Regulation could provide no-profit actors with an opportunity to challenge the Commission's determination of the intended level of protection, together with the regulatory decision that the uncertain risks posed by GMOs are worth running. By scrutinising the risk assessments conducted by EFSA, and by pointing to scientific gaps and persisting uncertainties, NGOs have an opportunity to argue that in light of the pervasive potential effects of GMOs, and taking all advantages, disadvantages and distributional stakes into consideration, the intended EU level of protection must be *very high*, the EU approach to GMO risk management must be *precautionary*, and scientific uncertainty must be *dispelled* in so far as possible. Against this background, societal actors can advocate a *low* threshold of acceptable risk in the GMO field. Through their requests for the internal review of GMO authorisations NGO actors can then challenge the evidence-based paradigm, pushing for further scientific evidence that GM varieties are *safe enough* for their risks to be socially acceptable.

This article endeavours to assess whether existing case law under the Aarhus Regulation has opened up any opportunities for civil society to challenge the decision that, in the face of scientific uncertainty, GMO risks meet the intended EU level of health and environmental protection. In other words, it seeks to establish whether the actions of NGOs under the Aarhus Regulation have resulted in any meaningful review of the Commission's exercise of its discretion, in accordance with the overarching tenets of the precautionary principle and the aim of a high level of health and environmental protection.[14]

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[13] On the technocratic shift of EU risk regulation, see inter alia Maria Weimer and Anniek de Ruijter (eds.) *Regulating Risks in the European Union. The Co-Production of Expert and Executive Power* (Hart Publishing, 2017), and Giulia Claudia Leonelli, 'The Glyphosate Saga and The Fading Democratic Legitimacy of European Union Risk Regulation', supra no. 1.

[14] On the notion of 'high level of protection' see article 3(3) TEU, article 114(3) TFEU, article 168(1) TFEU and article 191(2) TFEU. See also the Communication from the Commission on the Precautionary Principle, supra no. 2, at 7 and 8.

Section 2 analyses the positive developments underlying the two *TestBioTech* – T-177/13 and T-33/16 – cases.[15] Section 3 provides a concise overview of the evidentiary rules and standards of review applicable to judicial review of EU risk regulation, with a view to introducing the analysis of the following sections. Sections 4 and 5, on the other hand, explore the Court's failure to take the precautionary principle and scientific uncertainty seriously in Case T-177/13. Against this overall backdrop, section 6 puts forward an argument for different evidentiary rules and a different standard of review in Aarhus Regulation case law, advocating a clearer distinction between 'standard' action for annulment and annulment of a decision to reject a request for internal review. This is argued to be the only way forward to breathe some life into the Aarhus Regulation's provisions, ensuring some scrutiny of the level of protection achieved and nudging the Commission to take the precautionary principle seriously in the GMO field.

2. Procedural Aspects And Admissibility of Actions Under Article 12 of The Aarhus Regulation.

In case T-177/13 the Court rejected the Commission's submission that the action was inadmissible in so far as the Aarhus Regulation does not allow for judicial review of the authorisation decision itself.[16] In this case the three NGO applicants TestBioTech eV, European Network of Scientists for Social and Environmental Responsibility eV and Sambucus eV sought the annulment of a 2013 Commission's decision,[17] whereby their request for internal review of the authorisation of soybean MON 87701 x MON 89788 had been rejected. The Court refused the Commission's interpretation of the NGOs' action as an action for annulment of the GMO authorisation 'through the back door'.[18] As already mentioned, actions under article 12 of the Aarhus Regulation can only lead to the annulment of a decision rejecting a request for internal review. This, however, does not result in the annulment of the act which is the object of the request for internal review; the latter could only be challenged by applicants

[15] Case T-177/13 *TestBioTech eV and Others v European Commission* EU:T:2013:736 (Appeal Case C-82/17 P, in progress), and Case T-33/16 *TestBioTech eV v European Commission* EU:T:2018:135. On 05/05/2017 (Case T-173/17, in progress) TestBioTech eV deposited a further application for the annulment of a 2017 Commission's decision, whereby the latter rejected the NGO's request for internal review of the authorisation of genetically modified soybeans FG 72, MON 87708 and MON 87705 x MON 89788.
[16] Case T-177/13, para. 41.
[17] Decision of the European Commission of 3 January 2013 Concerning the Review of Commission Implementing Decision 2012/347/EU of 28 June 2012 Authorising the Placing on the Market of Products Containing, Consisting of or Produced From Genetically Modified Soybean MON 87701 x MON 89788, O.J. 2012 L 171.
[18] Case T-177/13, para. 41.

meeting the standing rules of article 263 TFEU.[19] Indeed, as the Advocate General pointed out in his Opinion, the internal review procedure itself targets administrative processes, without necessarily affecting their material outcome.[20]

Furthermore, in case T-33/16, the Court aligned to a broad interpretation of 'environmental law' and 'environmental protection', straightforwardly rejecting the Commission's claim that the internal review process and access to justice provisions laid out by the Aarhus Regulation should be limited to questions surrounding the 'state of the environment' and GM crop cultivation, as allegedly distinct from 'public health' matters and safety concerns on GM food and feed. In this case the NGO applicant TestBioTech eV sought the annulment of a 2015 letter from the Commissioner for Health and Safety, whereby the latter had refused the applicant's request for internal review of the authorisation of Pioneer's 305423 GM soybean.[21]

Not only did the Court clarify that the distinction between 'environmental' and 'public health' protection is artificial and legally unfounded, in the landscape of EU environmental law.[22] It also noted that the importation of GM varieties in the EU still implies that GM crops have been cultivated somewhere else; the environmental goals of the EU framework for the governance of GMOs, however, are not restricted 'to the protection of the natural environment within the European Union'.[23] Further than that, given that the use of GM feed may impact on animal health and welfare, authorisations of GM food and feed varieties cannot but fall within the remit of EU environmental law. This resulted in the annulment of the letter rejecting the applicants' request for internal review.

The Court's reasoning in these two cases has marked a step forward in the acknowledgment of NGO rights under the Aarhus Regulation, doing justice to the procedural dimension of public participation and access to justice in the field of environmental law. What remains to be seen, as anticipated since the introductory section, is whether *procedural* access to justice may in fact enable NGOs to dispute the *substantive* outcome of their request for internal review. Has the Court fleshed out an adequate standard of review, with a view to scrutinising the Commission's decision to reject a request for internal review? The next section introduces the notions which are relevant to answering this question, paving the way for the enquiry of the

[19] See article 263 TFEU.
[20] Opinion of Advocate General Szpunar in Appeal Case C-82/17 P (in progress) *TestBioTech eV and Others v European Commission* EU:C:2018:837, paras. 31, 39 and 40. EU institutions may then *amend, suspend, withdraw* or *repeal* acts adopted by them; see Case T-177/13, para. 44.
[21] Case T-33/16, paras. 2 to 4.
[22] Case T-33/16, paras. 62 ff.
[23] Ibid., para. 66.

following sections. Sections 4 and 5 will then turn to a more in-depth analysis of case T-177/13, together with the specific grounds for the Court's rejection of this action for annulment.

3. Substantive Aspects: Burden of Proof, Standard of Review And The Commission's Margins of Discretion.

Any enquiry into the standards of review deployed in the field of EU risk regulation is intertwined with an analysis of the Commission's margins of discretion in decision-making.[24] The Court of Justice has traditionally acknowledged that the Commission is endowed with broad discretionary powers in cases involving complex technical-scientific assessments; review by the Court must then be limited 'to examining whether the institution committed a manifest error of assessment or misuse of power or manifestly exceeded the limits of its power of appraisal'.[25] This has resulted in a deferential standard of scrutiny.[26] The Court has throughout the years focused on assessing compliance with all relevant procedural conditions, and has carved out a narrow interpretation of 'manifest error of assessment'. The Commission has traditionally been understood to incur a manifest error of assessment when its decision is found to be arbitrary and completely unsubstantiated; to this end, the Court will usually limit itself to an analysis of the overall rational coherence and consistency between the available evidence and the final measure.[27]

The application of this deferential standard of review by the Court has aimed at safeguarding the boundaries of the Commission's administrative discretion.[28] Nonetheless, it has also opened up spaces for precautionary decision-making, enabling the Commission to enact

[24] In the same perspective, see Christopher Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation' (2014) *Common Market Law Review* 51(4), 424-454.

[25] See Case C-331/88 *Ex Parte Fedesa and Others* EU:C:1990:391, para. 14; and Case C-157/96 *Ex Parte National Farmers' Union and Others* EU:C:1998:91, para. 39.

[26] See inter alia Case C-180/96 *United Kingdom* v. *Commission* EU:C:1998:192; Joined Cases C-154 and 155/04 *Ex Parte Alliance for Natural Health and Others* v. *Secretary of State for Health* EU:C:2005:449; Case C-326/05 *Industrias Químicas del Vallés* v. *Commission* EU:C:2007:443; Case C-79/09 *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute* EU:C:2010:803; Case C-343/09 *Afton Chemical Limited* v. *Secretary of State for Transport* EU:C:2010:419; and Case C-15/10 *Etimine v. Secretary of State for Work and Pensions* EU:C:2011:504.

[27] See for instance Case C-79/09 *Gowan Comércio*, paras. 46 and 71 ff.

[28] The aim is not the one of safeguarding or enhancing precautionary decision-making, as such. This is proved by the more stringent standard applied to the review of *national* precautionary measures. For the same view, see Christopher Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation', supra no. 26, 431 ff.

precautionary measures as long as it could rely on scientific uncertainty, scientific complexity and diverging risk assessments.

In its full and authentic understanding, the precautionary principle applies when in the face of insufficient, inconclusive or imprecise scientific evidence it is impossible to determine with certainty the existence and extent of a risk, but the likelihood of real harm to the environment and public health persists;[29] the risk manager is called upon to enact precautionary measures in so far as the uncertain risk may not meet the intended EU level of protection.[30] Under the most common scenario, market actors meeting the standing criteria of article 263 TFEU have sought the annulment of precautionary risk regulation on the grounds that the Commission had failed to take into due consideration 'sound' scientific evidence, allegedly committing a manifest error of assessment. However, the Court's acknowledgment of the Commission's broad discretion and its non-intrusive standard of review has enabled the Commission to rely on prudential risk assessments, minority scientific opinions or persisting scientific uncertainty without incurring a manifest error of assessment. This has, albeit indirectly, safeguarded precautionary risk regulation at EU level.

This situation has gradually evolved throughout the years, with the Court increasingly focusing on the technical-scientific studies substantiating the final measure and the specific scientific evidence relied upon by the Commission. This 'scientification' of judicial review[31] has built on, and yet significantly expanded, the traditional evaluation of the plausibility of the final decision, and the assessment of whether the Commission complied with all relevant procedural guarantees.[32] Specifically, the Court has expanded its review of whether the Commission complied with its duty to act diligently, whereby it is bound to examine 'carefully and impartially all the relevant facts of the individual case […]'.[33] Judicial review of the 'relevant facts of the individual case' that should have been taken into consideration in the final decision has thus resulted in an intrusive scrutiny of the scientific evidence relied upon by the

[29] See inter alia Case T-13/99 *Pfizer*, paras. 140, 142, 144 and 160; Case C-333/08 *Commission v France* EU:C:2010:44, paras. 91, 92 and 93; and Case C-343/09 *Afton Chemical*, para. 61.

[30] See the Communication from the Commission on the Precautionary Principle, supra no. 2, in particular at 7, 8, 9 and 12. See also the GFL, supra no. 2, recitals (8), (21) and (32) and articles 1(1), 5(1), 7(1) and 7(2).

[31] See Patrycja Dabrowska-Klosinska, 'Risk, Precaution and Scientific Complexity Before the Court of Justice of the European Union', in Lukasz Gruszczynski and Wouter Werner (eds.), *Deference in International Courts and Tribunals* (Oxford University Press 2014), 192-208, 205 ff.

[32] Ibid.

[33] See for instance Case C-691/15 P *European Commission* v. *Bilbaína de Alquitranes SA and Others* EU:C:2017:882, at para. 35, quoting Case C-269/90 *Technische Universität München* v. *Hauptzollamt München-Mitte* EU:C:1991:438, para. 14; Case C-326/05 *Industrias Químicas del Vallés*, para 77; Case C-405/07 P *Netherlands* v. *Commission* EU:C:2008:613, para 56; and Case C-77/09 *Gowan Comércio*, para 57. For an in depth analysis of this point, see Giulia Claudia Leonelli, 'The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: *Bilbaína*', supra no. 1.

Commission. This has occasionally lead to a finding of manifest error of assessment, and to the annulment of the acts challenged by market actors.[34]

This has marked a partial shift from a procedural, traditionally deferential standard of scrutiny, to a quasi-substantive standard,[35] or 'evidence-based judicial reflex'.[36] This 'quasi-substantive' turn is, arguably, hard to reconcile with the balance between technical expertise and political legitimacy underlying EU risk regulation;[37] were 'sound' scientific evidence all that EU institutions had to take into consideration, technical experts would have been entrusted with risk management and final decision-making powers. Further than that, a 'quasi-substantive' standard of review is arguably problematic in the light of the precautionary principle and overarching goal of a high level of protection in the EU. Nonetheless, this move has certainly come as welcome news for the advocates of evidence-based risk regulation; the latter have throughout the years argued in favour of narrowing down the Commission's broad administrative discretion, advocating a thorough review of the scientific 'soundness' of EU risk regulation.[38]

Against this overall background, the attempts to limit the Commission's discretion and overcome the traditional procedural standard of review have so far gone hand in hand with an evidence-based perspective; in other words, EU acts have mostly been challenged for not being based on 'sound' science.[39] What happens, however, in cases where a decision is challenged for *not* being *precautionary enough*, and for being grounded on *non-prudential* risk

[34] See Case T-456/11 *International Cadmium Association and Others v. Commission* EU:T:2013:594, and Case C-691/15 P *Bilbaína.*

[35] For more details on this gradual, albeit discontinuous, shift towards 'quasi-substantive' review, see Giulia Claudia Leonelli, 'The Fine Line Between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: *Bilbaína*', supra no. 1.

[36] Alberto Alemanno, 'The Emergence of the Evidence-Based Judicial Reflex. A Response to Bar-Siman-Tov's Semi-Procedural Review' (2013) 1 *Theory and Practice of Legislation*, 1.

[37] Most famously, see Case T-13/99 *Pfizer*, para. 149. See also the Communication from the Commission on the Precautionary Principle, supra no. 2, at 15 and 21.

[38] See inter alia Alberto Alemanno, 'Case C-79/09, *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010' (2011) *Common Market Law Review* 48(5), 1329-1348; Alberto Alemanno, 'The Science, Law and Politics of Neonicotinoids and Bees. A New Test Case for The Precautionary Principle' (2013) *European Journal of Risk Regulation* 4(2), 191-207; Anne-May Janssen and Marjolein Van Asselt, 'The Precautionary Principle in Court. An Analysis of Post-*Pfizer* Case Law', in Marjolein Van Asselt, Esther Versluis and Ellen Vos (eds.), *Balancing between Trade and Risk. Integrating Legal and Social Science Perspectives* (Routledge 2013), 197-216; Anne-May Janssen and Nele Rosenstock, 'Handling Uncertain Risks: An Inconsistent Application of Standards?' (2016) *European Journal of Risk Regulation* 7(1), 144-154. More specifically, the advocates of evidence-based risk regulation have called for a thorough review of the margins of scientific uncertainty triggering precautionary action, and of the level of protection deemed appropriate by the risk manager.

[39] The opposite case – namely, the one of applicants challenging an EU act for *not* being precautionary – has been very rare. However – taking into consideration the stringent standing criteria of article 263 TFEU, and excluding the specific case of privileged applicants – it has been much easier for market actors producing or trading in hazardous products and processes to seek the annulment of EU acts, than it has been for NGOs and public interest groups.

assessments? How are we to interpret the 'manifest error of assessment' test, and what evidentiary rules should apply? How are we to outline the boundaries of the Commission's discretion, in these cases? What happens in the specific instance of actions under the Aarhus Regulation, as structurally distinct from other actions for annulment? These questions lie at the heart of the *TestBioTech* cases.

The crucial point emerging from case T-177/13 is the one surrounding the applicable evidentiary rules; it is thus unsurprising that the Advocate General's Opinion is confined to the second ground of appeal, whereby the appellants lamented that the General Court erred in law in its application of the burden of proof.[40] This aspect is, in turn, closely related to the issue of the standard of review deployed by the Court.

In case T-177/13 the applicants argued that they were *not* required, when submitting their request for internal review,[41] to prove that the modified soybean was *not* safe. Rather, they claimed that in so far as the scientific evidence they relied on raised legitimate and substantive doubts as to the safety of this GM variety, the burden of allaying any such concerns fell on the Commission.[42] This argument reflects a socially acceptable risk approach: it challenges the presumption that uncertain risks should be run in so far as they have not been 'soundly' established, and hints at the regulator's responsibility to persuade the public that a product or process meets the intended level of protection. The Court, however, reached the different conclusion that applicants must provide 'a set of material raising serious doubts as to the lawfulness of the authorisation decision'.[43]

This finding was complemented by the application of the traditional manifest error of assessment test, which obviously has a powerful impact on the framing of the burden of proof. The defendants in the case arguably feared an indirect review of the scientific evidence relied upon for the purposes of the authorisation; to put it differently, that the Court would question whether the controversial matters and scientific gaps highlighted in the applicants' request for review warranted further consideration through the internal review procedure, in light of the overarching goals of the GM Food and Feed Regulation.[44] However, building on the traditional acknowledgment of the Commission's broad discretion in cases of complex scientific assessments, the General Court opted for the application of the 'standard' manifest error of

[40] Opinion in Appeal Case C-82/17 P (in progress), para. 23.
[41] See supra, section 2, for some details on the case.
[42] Case T-177/13, para. 82.
[43] Ibid., see paras. 67 and 88 in particular.
[44] See paras. 72 to 76.

assessment test, stating that the evidence adduced by the applicant 'must be sufficient to make the factual assessments used in the act implausible'.[45]

The Advocate General reached the same conclusions in his Opinion. On the one hand, he emphasised the wide margins of the Commission's discretion in cases involving complex technical-scientific assessments.[46] On the other hand, focusing on the standard of proof for the applicants, he contended that a party seeking internal review 'should provide concrete and precise arguments which might be able to call into question the factual position on which the authorisation decision is based'.[47] Upon declaring that a 'presumption of veracity, completeness and accuracy' exists in respect of the authorisation decision,[48] he clarified that any request for an intense and thorough internal review should be based on arguments and evidence that would call such presumption into question.[49]

The next sections argue that the evidentiary rules and standard of review applied by the General Court and defended by the Advocate General deprive the access to justice provisions laid out in the Aarhus Regulation of any purpose. As the three NGOs maintained in their appeal to the Court of Justice, the General Court applied an 'incorrect and impossible burden of proof' on not-for-profit organisations and failed to take into consideration the NGOs' claim that significant scientific gaps persisted in risk assessment.[50]

The next section focuses on a range of complaints surrounding the interpretation and evaluation of scientific evidence that EFSA and the Commission had already taken into – some – consideration. Section 5 will then turn to a different set of complaints, pointing to scientific gaps in risk assessment and genuine scientific uncertainty; in these cases the applicants advocated further research by EFSA, claiming that the margins of scientific uncertainty and the potentially ensuing risks warranted further consideration by the EU institutions. In both instances, the evidentiary rules laid out by the Court and the application of the traditional manifest error of assessment test do not allow for any meaningful scrutiny of the Commission's decision to reject the applicants' request for a review of the GMO authorisation.

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[45] Paras. 77 and 78. In the same perspective, albeit with the aim of defending the Commission's adherence to a precautionary approach, see the Opinion of Advocate General Jääskinen in Case C-77/09 *Gowan Comércio Internacional e Servicos v Ministero della Salute* EU:C:2010:432, para. 74.

[46] Opinion in Appeal Case C-82/17 P (in progress), paras. 55 and 56.

[47] Opinion in Appeal Case C-82/17 P (in progress), para. 52.

[48] Opinion in Appeal Case C-82/17 P (in progress), para. 52. The Advocate General explained this presumption on the – rather shaky – grounds that 'it is in the very nature of these institutions [the Commission and EFSA] to be impartial'.

[49] Opinion in Appeal Case C-82/17 P (in progress), paras. 52, 68 and 69.

[50] Opinion in Appeal Case C-82/17 P (in progress), para. 22 and paras. 57 and following.

4. GMOs And Manifest Errors of Assessment (I). Cases Where Scientific Evidence Had Already Been Taken Into Account.

The applicants corroborated a number of their pleas and complaints by reference to evidence which had already been taken into some consideration throughout the GMO authorisation process. At the heart of these complaints lay a divergent framing and interpretation of the relevant scientific data and evidence; in other words, in their request for internal review and subsequent action for annulment, the applicants challenged the *prudential* nature of EFSA's risk assessment[51] and the Commission's compliance with the *precautionary principle* in its exercise of risk management.[52] This may be defined as an *Upper Austria* case[53] scenario; a case where no 'new' scientific evidence is being adduced, and the controversy boils down to a straightforward disagreement over the notion of intended EU level of protection in the GMO field. In *Upper Austria* the Republic of Austria and the Upper Austria region sought the annulment of a 2003 Commission's decision, rejecting their request for a derogation from the Deliberate Release Directive[54] on the grounds of article 114(5) TFEU; at the centre of this famous case was a divergent interpretation of the notions of 'acceptable risk' and 'intended level of environmental protection' in light of all available scientific data, as already evaluated by EFSA throughout the environmental risk assessments stage. Indeed, as the Advocate General and the Court concluded in this case, the scientific report Austria and Upper Austria were relying on did neither provide any new scientific evidence on the contamination risks that GMO cultivation may pose in Upper Austria, nor any new data on the potential impact on specific local ecosystems.[55]

In case T-177/13, the Court rejected all the complaints surrounding scientific evidence which had already been the object of some assessment by EFSA and the Commission. Unsurprisingly, the General Court held in various parts of the judgment that the applicants had not been able to prove any manifest error of assessment on the part of the Commission and had not provided any 'new' scientific evidence which could invalidate the Commission's decision.

[51] European Commission, Communication from the Commission on the Precautionary Principle, supra no. 2, 12 to 14.
[52] Ibid., 15 and 16.
[53] Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* EU:C:2007:510.
[54] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, O.J L 106/1 ('Deliberate Release Directive').
[55] Ibid., paras. 56 ff. See also the Opinion of Advocate General Sharpston in Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* EU:C:2007:285, paras. 22 and 117-118.

Nonetheless, a closer look at the case testifies that the Commission had not in its decision dealt with or answered all of the applicants' points in a satisfactory way. While the Commission convincingly answered the points raised in the first four parts of the first plea, substantiating its counter-arguments by reference to the risk assessment process, it merely dismissed some of the other complaints as unfounded, ignoring the scientific studies relied upon by the applicants and concluding that they were irrelevant or would not invalidate the final findings.

In the second part of the first plea, the applicants adduced evidence that EFSA had allowed Monsanto to 'base itself on the alleged slightness of the statistically significant differences across a broad cross-section of reference substances and on the ILSI database to mask the high number of statistical differences between the composition of the modified soybean and the composition of its conventional counterpart';[56] in other words, they claimed that Monsanto had generated a broad range of data to produce scientific noise and mask the differences between the GM soybean and its comparator.[57] In its answer, however, the Commission clarified that reference varieties with a history of safe use 'are not used to detect possible differences between the genetically modified plant and its conventional counterpart, as the applicants seem to imply. The statistical comparison between the genetically modified crop and its conventional counterpart is independent of the non-genetically modified varieties, so that no statistical noise exists, contrary to what the first applicant states'.[58] On these grounds the Commission adequately disproved the applicants' argument, allaying their concerns on any statistical noise vis-à-vis the finding of substantial equivalence.

This did not occur, however, with many other points raised by the applicants. In the fifth part of the first plea, the applicants referenced scientific research showing that spraying with glyphosate and maintenance pesticides may have unintended effects when biotic or abiotic stressors intervene. Although observations on abiotic stressors had shown statistically significant differences in 9 cases of comparison, the Commission concluded that those cases were unproblematic and that the scientific literature presented by the applicants was irrelevant, as it referred to the cultivation of other varieties.[59] The General Court found that the applicants had failed to produce sufficient material to establish that the Commission had committed a manifest error of assessment.[60] In a similar vein, the Court argued that the applicants had failed to provide any new or relevant scientific evidence that would change the conclusions on the

[56] Case T-177/13, para. 127.
[57] Ibid., para. 131.
[58] Ibid., para. 134.
[59] Ibid., paras. 159 to 168.
[60] See specifically paras. 165 to 168.

toxicity assessment of the GM variety, the selectivity of Cry proteins and the synergistic or combinatorial effects of glyphosate treatment, Bt toxins and Cry proteins under specific environmental conditions.[61] The applicants lamented that the Commission had ignored the scientific studies they were relying upon,[62] and that it had not meaningfully dealt with any of their specific criticisms.[63] While agreeing that the Commission's reasons were very succinct, in so far as they were limited to a finding that the scientific evidence provided no new information,[64] the General Court held that the applicants had not been able to meet the burden of proof and demonstrate a manifest error of assessment.[65]

Against this background, it is reasonable to conclude that whenever a divergent evaluation or interpretation of scientific evidence is at stake, NGO applicants will be caught in the *Upper Austria* slippery slope. Just like under Article 114(5) TFEU case law, or under the GMO safeguard clauses,[66] they will have to provide 'new' and 'significant' scientific evidence on the risks posed by a GMO variety. If they are not able to do so, they will not have proved a manifest error of assessment; this will occur regardless of the Commission's weak – or convincing – claim that their request for internal review was scientifically and legally unfounded, and that the scientific evidence adduced had already been taken into due consideration.

This brief analysis sheds some light on the problems associated with the 'standard' manifest error of assessment test, as applied under the umbrella of the Aarhus Regulation. If the burden of proof is so high on the applicants, the latter will never be able to challenge the Commission's determination of the intended EU level of protection, pushing for further evidence that GM varieties are sufficiently safe to comply with the EU threshold of acceptable risk. In so far as the applicants are expected to prove that the Commission made a manifest error of assessment, the Commission will be shielded from any duty to dispel public concerns, proving that the applicants' request for an internal review of the GMO authorisation did not warrant any further consideration. This, however, directly contradicts the Advocate General's acknowledgment that the competent institution should 'demonstrate that the [NGOs'] argument[s] [are] clearly

[61] Paras. 171 ff.
[62] Para. 194.
[63] Para. 211.
[64] Para. 205.
[65] Para. 216.
[66] See article 23 of Directive 2001/18/EC ('Deliberate Release Directive'), and article 34 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Foods O.J. L 268/1 ('GM Food and Feed Regulation').

unsubstantiated',[67] given that the internal review procedure 'exists to establish whether there are elements that could have been overlooked in the course of the authorisation procedure'.[68] This burden of proof and standard of scrutiny can neither do justice to the socially acceptable risk approach, nor to the NGO applicants' requests for internal review. As the next section shows, this is even clearer in cases of genuine scientific uncertainty and in the lack of specific risk assessments.

5. GMOs And Manifest Errors of Assessment (II). Scientific Gaps and Cases of Genuine Scientific Uncertainty.

A number of complaints in Case T-177/13 pointed to scientific gaps in EFSA's assessment; in other words, the applicants lamented that EFSA had omitted to undertake specific risk assessments.[69] By the fourth part of their second plea, the applicants submitted that the Commission had not addressed their point on the potential implications of processing the GM soybean; indeed, EFSA had not conducted any assessment of the effects of processing or cooking the GM variety.[70] The Commission merely stated that, in light of the comparative biological analysis, no additional data were needed on the impact of processing. The Court found that the applicants had not provided any scientific evidence raising serious doubts as to the lawfulness of the authorisation, i.e. any scientific evidence supporting the argument that further analyses of the uncertain implications of processing would be needed.[71]

Equally, in the third part of the second plea, the applicants highlighted that EFSA had omitted to require any assessment of the synergistic and combinatorial effects of spraying the GM soybean with glyphosate and maintenance pesticides; they further stressed that a finding of substantial equivalence of the GMO variety to its conventional counterpart cannot constitute a legitimate ground to omit all appropriate risk assessments.[72] Upon arguing that toxicity assessments must be determined on a case-by-case basis, so that the possibility of a limited toxicity assessment should not be ruled out, the General Court reached the conclusion that the applicants in the case had not been able to demonstrate a manifest error of assessment in the

[67] Opinion in Appeal Case C-82/17 P (in progress), para. 47.
[68] Opinion in Appeal Case C-82/17 P (in progress), para. 32.
[69] Opinion in Appeal Case C-82/17 P (in progress), para. 22 – referencing the five grounds of appeal.
[70] Case T-177/13, para. 221.
[71] Ibid., paras. 223 and 224.
[72] Ibid., para. 227. Indeed, it is worth underlining that the difference between the two lies at the heart of the EU – process-based – regulatory framework for the governance of GMO risks.

Commission's examination and answer to their request for review.[73] In other words, the Court ruled that the applicants had failed to scientifically prove why and how EFSA should have conducted a thorough toxicity assessment.

Perhaps most worryingly, the same reasoning was applied to the applicants' complaints on EFSA's failure to investigate the effects of the GM soybean on the reproductive system, and the potential transfer of the GMO's biologically active compounds to animal or human tissues through consumption.[74] The Commission had rejected this point on the grounds that EFSA had not considered any specific endocrinological studies to be necessary, and that none of the studies referenced by the applicants had been soundly corroborated to date; the General Court reiterated that the applicants had not produced any scientific evidence challenging the Commission's position, and had therefore not demonstrated a manifest error of assessment on its part.[75] The same also occurred with the third plea,[76] whereby the applicants lamented EFSA's failure to conduct an assessment of the allergenic risks of the GM soybean for infants. Although this very omission breached the recommendations laid out in EFSA's own 2010 Scientific Opinion on Allergenicity, the Court still noted that EFSA had not found any further studies to be necessary; the applicants' complaint, on the other hand, was rejected on the grounds that they had not proved any manifest error of assessment.[77]

In these instances, the Court clearly got caught in a paradoxical line of reasoning. This set of complaints surround cases of structural scientific uncertainty and complexity, which the applicants considered would have warranted further consideration through the internal review process and a request to EFSA to conduct further assessments. In the lack of scientific data on the specific GM variety, and in so far as EFSA had not conducted all assessments, it was in fact impossible for the applicants to scientifically prove a manifest error of assessment – namely, that those assessments would be scientifically needed. All that the applicants could do was pointing to the margins of scientific uncertainty, as substantiated by different scientific studies and evidence on other GM varieties. Nonetheless, this was exactly the reason why these cases warranted further consideration through the internal review process;[78] by pointing to significant scientific gaps and EFSA's failure to conduct specific risk assessments, the

[73] Para. 229.
[74] Para. 236 ff.
[75] Paras. 243 and 244.
[76] Paras. 258 ff.
[77] See paras. 271 to 274.
[78] In this respect, see supra no. 68 for a reference to the Advocate General's acknowledgment that the internal review procedure 'exists to establish whether there are elements that could have been overlooked in the course of the authorisation procedure'.

applicants put forward a compelling case in favour of internal review, arguing that the Commission had committed a manifest error of assessment in rejecting their request.

On the other hand, the Court's and Advocate General's interpretation completely miss the point. Requesting the applicants to scientifically prove a manifest error of assessment, in the face of scientific uncertainty, is just like requesting regulators to scientifically prove the seriousness and extent of a risk, prior to taking any precautionary measures:[79] this would make the precautionary principle nugatory. Indeed, as already mentioned, the precautionary principle applies when in the face of insufficient, inconclusive or imprecise scientific evidence it is impossible to determine with certainty the existence and extent of a risk, but the likelihood of real harm to the environment and public health persists.[80]

Against this backdrop, the burden of proof on NGO actors is incorrect and impossible to meet in cases where significant scientific gaps persist in risk assessment.[81] Yet again, this directly contradicts the Advocate General's claims that 'the burden of raising and presenting the issues, allocated to the party requesting review […], should not be too strict for the purposes of launching the internal review procedure'.[82]

6. Advocating Different Evidentiary Rules And A Different Standard of Review: Legal Grounds and Precedents.

As the last two sections have shown, the application of the 'standard' manifest error of assessment test within Aarhus Regulation case law will never result in any meaningful scrutiny of a decision to reject a request for internal review. For this reason, it will never enable NGOs to argue that in light of the potentially pervasive effects of GMOs, and taking all advantages, disadvantages and distributional stakes into consideration, the intended EU level of protection must be *very high*, the EU approach to GMO risk management must be *precautionary*, and scientific uncertainty must be *dispelled* in so far as possible.

From this perspective, the manifest error of assessment test and the traditional acknowledgment of the Commission's broad discretion in cases involving complex scientific evaluations deprive

[79] The latter point was at the centre of the applicants' – unsuccessful – arguments in Case T-13/99 *Pfizer*. See paras. 164 and 383 therein.

[80] See supra, no. 29. On the precautionary principle, as applicable to the GMO field, see Directive 2001/18/EC ('Deliberate Release Directive'), recital (8) and article 4(1); and Regulation (EC) No. 1829/2003 ('GM Food and Feed Regulation'), recital (32) and article 1(a).

[81] Opinion in Appeal Case C-82/17 P (in progress), para. 22 and paras. 57 and following.

[82] Opinion in Appeal Case C-82/17 P (in progress), para. 50. See also para. 37 therein.

the Aarhus Regulation access to justice provisions of any real purpose. Whether or not the Commission's arguments that all evidence has been taken into due account are substantiated, and whether or not significant scientific gaps persist in risk assessment, NGO applicants will only succeed in their action if they can positively prove a manifest error of assessment. Despite persisting scientific uncertainty, the Court will never truly assess whether the applicants' request for internal review warranted further consideration; the applicants will neither have the opportunity to challenge the level of protection pursued in the GMO field, nor the Commission's compliance with the precautionary principle in the exercise of its risk management functions. As a result, neither the notion of prudential risk assessment nor the overarching tenets of the precautionary principle are being taken seriously.

The argument in favour of different evidentiary rules and a different standard of review goes to the heart of the evidence-based versus socially acceptable risk approach dichotomy. Should the uncertain risks posed by GMOs be run unless and until they have been scientifically established, or should risk managers put forward a convincing case that GMOs meet the intended EU level of protection? Crucially, should a decision to reject a request for internal review be annulled when NGO applicants have proved that a GMO is *not* safe, or when the Commission, in the face of persisting scientific uncertainty, has not been quite able to prove that it is *safe enough*? The General Court and the Advocate General undoubtedly took the former view.[83] However, the latter scenario appears to be the only way forward to breathe some life into the Aarhus Regulation access to justice provisions. While this would mark a radical shift away from a deferential approach to the Commission's margins of appreciation in precautionary risk governance, it would neither be a legally unfounded nor an unprecedented move.

Starting from the legal grounds for this argument, it is worth underlining that both the General Court and Advocate General have drawn a distinction between judicial review of GMO authorisations, on the one hand, and judicial review of a decision rejecting a request for internal review, on the other. A clear difference exists between a 'standard' action for annulment and an action for the annulment of a decision rejecting a request for internal review. Whilst the applicants were indirectly challenging the lawfulness and merits of the GMO authorisation, the Court clarified that it would only be looking at the GM soybean authorisation in so far as this

[83] For a similar evidence-based perspective, albeit in a different context, see Alberto Alemanno, 'Case C-79/09, *Gowan Comércio Internacional e Servicos Lda* v. *Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010', supra no. 38, at 1344, arguing that scientific uncertainty should not legitimate precautionary action regardless of 'when and by whom the scientific uncertainty requirement has been identified'. For the opposite view see Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation', supra no. 5.

could be relevant to a finding of lack of powers, infringement of essential procedural requirements, infringement of the Treaties or legal rules and misuse of powers in the Commission's *decision to reject their request for internal review*.[84] To put it differently, and as already explained, the annulment of a decision rejecting a request for internal review does *not* result in, and is structurally distinguished from, the annulment of the act which is the object of the request for internal review.

The Advocate General explored this aspect in further detail in his Opinion. Whilst acknowledging the difference between 'standard' actions for annulment and actions for annulment under article 12 of the Aarhus Regulation, however, he did not elaborate further on it; in other words, he did not consider such difference to be relevant to the question of the applicable evidentiary rules and standard of scrutiny. Focusing on the substantive grounds for a request for internal review to be accepted, he noted that no precise criteria may be inferred from the wording of article 10.[85] Turning to the intensity of the Court's review in case of a subsequent action for annulment, he also found that article 12 does not provide any indications.[86] In this light, he argued in favour of the traditional evidentiary rules and manifest error of assessment test, as applicable under 'standard' actions for annulment.

While this position is certainly tenable, it does not do any justice to the structural differences between actions for annulment under article 263 TFEU and article 12 of the Aarhus Regulation; these should, arguably, reflect on the applicable burden of proof and standard of scrutiny.[87] From this different perspective, and focusing on the specific case of the annulment of a decision rejecting a request for internal review, it is legitimate to suggest that the *legally* relevant manifest errors of assessment[88] ought to be the ones that the Commission may have committed in its decision that a *request for internal review was unfounded* and *did not warrant further consideration*. This opens up spaces for a teleological interpretation of the Aarhus Regulation access to justice provisions in light of the precautionary principle.[89] In so far as the annulment

[84] Case T-177/13, paras. 56, 59, 60 and 109.
[85] Opinion in Appeal Case C-82/17 P (in progress), para. 26.
[86] Opinion in Appeal Case C-82/17 P (in progress), para. 54.
[87] In fact, there does not appear to be any reason to draw a distinction between the two forms of action for annulment if the applicable evidentiary rules and standard of scrutiny are exactly the same.
[88] On the notion of *legally* relevant manifest error of assessment see the Opinion of Advocate General Kokott in Case C-343/09 *Afton Chemical Ltd v Secretary of State for Transport*, EU:C:2010:258, para. 30.
[89] In this respect, it is curious to note the Advocate General's own acknowledgment that 'the purpose of the internal review procedure is […] to reconsider the procedure that led to the authorisation decision, in order to check whether new information or the re-evaluation of known information might justify the revision of the authorisation decision. This purpose is perfectly in line with the precautionary principle in environmental law'; see Opinion in Appeal Case C-82/17 P (in progress), paras. 40 and 41. In this sense, the Advocate General has – indirectly – acknowledged that the internal review procedure and subsequent action for annulment, as provided for under the Aarhus Regulation, are an expression of the precautionary principle.

of a decision rejecting a request for internal review is different from the annulment of a GMO authorisation, the *legally* relevant manifest errors of assessment need not be the same which would make the GMO authorisation arbitrary or scientifically implausible; equally, the burden of proof need not be the – high – one which would have to be met by the applicants if they were seeking the annulment of the GMO authorisation.

As the NGOs argued in case T-177/13 and in their appeal, a request for internal review should simply raise legitimate and substantive doubts as to the *safety* of a GM variety. If the request for internal review is rejected and the annulment of the relevant decision is being sought, the applicants should merely prove that the Commission committed a manifest error of assessment in deciding that, despite persisting scientific uncertainty, their request did not warrant further investigation;[90] from this perspective, a failure to take controversial scientific evidence into due consideration and a failure to conduct substantial safety assessment should certainly lead to a finding that manifest errors of assessment were committed in the decision to reject the applicants' request. Symmetrically, the Commission should be able to show that the request did not warrant further consideration, as all scientific evidence had already been taken into due consideration and all risk assessments had been exhaustively conducted by EFSA; ultimately, the Commission should be able to make a convincing case that the internal review procedure was unnecessary.

This different interpretation lowers the requisite legal standard for NGO applicants to prove a manifest error of assessment, re-distributing the burden of proof between the applicants and the Commission; a fairer balance could thus be struck between the applicants' duty to scientifically substantiate their claims on GMO risks and the Commission's duty to dispel scientific uncertainty and allay societal concerns. Drawing a more subtle and arguably clearer distinction between 'standard' actions for annulment and actions under the Aarhus Regulation could then pave the way for a different understanding of the manifest error of assessment test, re-interpreting the Aarhus Regulation access to justice provisions in light of the precautionary principle. By scrutinising the risk assessments conducted by EFSA, and by pointing to scientific gaps and persisting uncertainties, NGOs would have a real opportunity to request further scientific evidence that GM varieties are *safe enough* and challenge the decision that, in the face of scientific uncertainty, GMO risks *meet* the *intended EU level of protection* and are *socially acceptable*.

[90] Indeed, the Court underlined that the applicants' pleas in law should have only targeted the Commission's decision to reject their request for internal review – rather than the underlying GMO authorisation process and the Commission's authorisation decision. See Case T-177/13, paras. 59 and 60.

Not only would this nudge the Commission to take the precautionary principle seriously;[91] it would also, and crucially, do justice to the NGO applicants' claims. As the Court increasingly embraces a 'quasi-substantive' standard of scrutiny, it is unclear why a deferential, procedural standard of review and a narrow application of the manifest error of assessment test should operate in cases under the Aarhus Regulation. If the Court has come to thoroughly scrutinise the scientific evidence relied upon by the Commission, and if the boundaries of the Commission's administrative discretion have been correspondingly narrowed down, then compliance with the precautionary principle and the pursuit of a high level of protection should be equally reviewed. In this perspective, the overarching tenets of the precautionary principle should act as a constraint on the Commission's discretion, when deciding to reject a request for internal review under the Aarhus Regulation.

Secondly, turning to the issue of precedents, it is worth noting that the Court took a similar perspective in the *Paraquat* – T-229/04 – case.[92] In this case the Kingdom of Sweden sought and succeeded in obtaining the annulment of Commission Directive 2003/112/EC,[93] authorising the use of paraquat as an active substance. Sweden alleged the infringement of a range of procedural provisions, suggesting that scientific evidence had not been taken into due consideration by the Commission, as well as breaches of substantive legal provisions, the precautionary principle and the principle that a high level of environmental and public health protection must be ensured in the EU.[94]

The first set of pleas in *Paraquat* brings us back to the case of a divergent framing and interpretation of the relevant scientific data.[95] Indeed, the Commission argued in its defence that all the evidence adduced by Sweden on the potential link between the use of paraquat and the development of Parkinson disease had already been taken into account throughout the authorisation process;[96] in other words, Sweden was not relying on any 'new' scientific evidence. Whilst some specific procedural irregularities could be identified in the processing of the paraquat dossier, the Court suggested – at a more general level – that the Commission

[91] See the Court's own – theoretical – acknowledgment that the Commission is bound by the precautionary principle at paras. 86, 87, 104, 105 and 106 of Case T-177/13.
[92] Case T-229/04 *Sweden v Commission* EU:T:2007:217. See also Christopher Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation', supra no. 24.
[93] Commission Directive 2003/112/EC of 1 December 2003 Amending Council Directive 91/414/EEC To Include Paraquat As An Active Substance, O.J. L 321, no longer in force.
[94] Case T-229/04 , para. 54.
[95] See supra section 4.
[96] Case T-229/04, paras. 83 to 88 and 96-97.

had in fact failed to take some controversial scientific evidence referenced by Sweden into due consideration.[97] This resulted in Sweden's plea being accepted.

The second set of pleas, on the other hand, pointed to scientific gaps in the risk assessment.[98] Sweden argued that the Commission, in the face of persisting uncertainty, had not put forward any convincing scientific case that the acceptable operator exposure level ('AOEL') would be met and that the use of paraquat would not pose serious risks to animal health. Thus, it contended that the Commission had not substantiated its claim on paraquat's *safety* to the requisite legal standard, breaching both the precautionary principle and the principle that a high level of protection must be achieved.[99] The Court accepted Sweden's contention, arguing that Directive 91/414[100] must be interpreted in light of the precautionary principle and that the Commission should have 'established beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid out [in the Directive]';[101] it also considered that Sweden had relied upon 'solid evidence which may reasonably raise doubts as to the safety of paraquat'.[102]

To draw some conclusions, in *Paraquat* the Court took the view that the Commission had not rebutted Sweden's arguments, allaying Member States' concerns and persuading them of paraquat's safety. This sheds further light on the socially acceptable risk line of reasoning which has been advocated in this section, beyond the evidentiary rules laid out in case T-177/13 and the manifest error of assessment test. From this perspective, *Paraquat* substantiates the claim that a different standard of scrutiny could be developed and applied to Aarhus Regulation case law.

7. The Way Forward: The Case For Precautionary GMO Governance.

Making sure that the voice of NGO applicants and civil society is heard is all the more important in the politically and socio-economically contested case of agricultural biotechnologies; indeed, all latest actions under the Aarhus Regulation have targeted decisions

[97] Case T-229/04, paras. 102 to 126.
[98] See supra section 5.
[99] Case T-229/04, paras. 139 ff.
[100] Council Directive 91/414/EEC of 15 July 1991 Concerning The Placing of Plant Protection Products on The Market, O.J. L 230, no longer in force.
[101] Case T-229/04, paras. 170 and 227.
[102] Ibid., paras. 181 to 185.

rejecting a request for internal review of GMO authorisations. Societal stakeholders, consumers and citizens at the national and EU-wide level have repeatedly made the point that the uncertain risks posed by GMOs are not worth running; the Commission, however, does not seem inclined to take the notions of socially acceptable risk and precautionary risk governance seriously. In this sense, as already explained, the governance of GMOs epitomises an unresolved disagreement over the boundaries and scope of the notion of 'acceptable risk'.

As new techniques of genetic manipulation are developed and new sources of uncertain risks emerge,[103] paying due regard to NGO applicants and public opinion will get increasingly important. Access to justice under the Aarhus Regulation could then play a key role to revive a socially acceptable risk approach to GMO governance, helping NGOs challenge the presumption that uncertain risks must be run as long as they have not been scientifically proved. Against this backdrop, and in this perspective, it is to be hoped that the Court of Justice will accept the appellants' pleas in law, setting aside the Judgment of the General Court and annulling the Commission's decision.

Fleshing out an appropriate standard of review in cases under the Aarhus Regulation will certainly prove challenging. Nonetheless, a fairer balance should be struck between the Commission's margins of discretion, on the one hand, and the public interest rationale underlying the Aarhus Regulation, on the other. To this end, due consideration should be given to the special nature of the actions under Article 12 and to the precautionary principle and pursuit of a high level of protection, as enshrined in the Treaties.

No amount of precaution will ever make the scientific evidence adduced by the applicants 'new', as Advocate General Sharpston noted in her Opinion in *Upper Austria*;[104] nor will it enable the applicants to scientifically prove a manifest error of assessment, as traditionally understood.

However, the time has come to carve out a new interpretation of *legally* relevant manifest errors of assessment, paving the way for a genuine debate on precautionary GMO governance. The time is ripe to get back to the democratic and political foundations of EU risk regulation, beyond 'sound' science.[105]

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[103] On the challenges posed by the application of new 'mutagenesis' techniques, see Case C-528/16 *Confédération Paysanne and Others v Premier Ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt* EU:C:2018:583.

[104] Opinion of Advocate General Sharpston in Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission*, para. 134.

[105] Giulia Claudia Leonelli, 'The Glyphosate Saga and The Fading Democratic Legitimacy of European Union Risk Regulation', supra no. 1.